IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KEY PHARMACEUTICALS, INC.	:	CIVIL ACTION
v.	:	
ESI-LEDERLE, INC.	:	NO. 96-1219

MEMORANDUM OF DECISION

THOMAS J. RUETER
United States Magistrate Judge

August 29, 1997

I. INTRODUCTION

Plaintiff, Key Pharmaceuticals, Inc., owns a patent entitled "Controlled Release Potassium Chloride", U.S. Patent No. 4, 863,743 (hereinafter the '743 patent). Since 1986, Key has practiced this patent to produce a 20mEq sustained-release potassium chloride tablet, called K-Dur 20, which is used to treat persons who have potassium deficiency problems. The '743 patent has an expiration date of 2006. K-Dur 20 is the most widely used potassium supplement in the United States today. It has been estimated that as of 1996, the brand has nearly a 40% market share of all new potassium chloride prescriptions.

Plaintiff maintains that the dominance of K-Dur 20 in the market place results from special qualities that other potassium supplements do not possess. For example, patients only have to ingest K-Dur 20 tablets twice a day and they do not have the bad taste problems that inhibit compliance with liquid forms of potassium chloride. Moreover, K-Dur 20 tablets dispense into microcapsules when ingested so that intestinal problems are greatly decreased compared to other treatment approaches which use solid forms of potassium chloride.

On or about November 3, 1995, Upsher-Smith Laboratories, Inc., a Minnesota pharmaceutical company, filed an Abbreviated New Drug Application ("ANDA") with the

Food and Drug Administration ("FDA") seeking approval for commercial sale of a product called Klor-Con M, a 20 mEq extended-release potassium chloride tablet product. On December 15, 1995, plaintiff, Key Pharmaceuticals, Inc., filed an action in the United States District Court for the District of New Jersey, asserting that its '743 patent is infringed by Upsher-Smith's filing of the ANDA for the Klor-Con M tablet. The case was assigned to the Honorable William H. Walls, and docketed at Civil Action No. 95-6281. On or about July 24, 1997, the parties settled this case. The settlement agreement was not filed with the court, nor were the settlement terms placed on the record. On or about July 29, 1997, Judge Walls dismissed the case as settled. On or about March, 1997, Upsher-Smith received approval from the FDA to market its Klor-Con M Tablet. To date, Upsher-Smith has not sold the tablets commercially.

On or about December 29, 1995, defendant ESI-Lederle, Inc. filed an ANDA with the FDA, seeking approval for commercial sale of a product called Micro-K 20, a 20 mEq extended-release potassium chloride tablet product. On February 16, 1996, plaintiff, Key Pharmaceuticals, Inc., filed the above-captioned action in this court asserting that its '743 patent is infringed by ESI-Lederle's filing of the ANDA for the Micro-K 20 tablet. The case is assigned to the Honorable Jan E. DuBois. To date, ESI-Lederle, Inc. has not received approval from the FDA to market its Micro-K 20 tablet. Consequently, it has not sold the product commercially.

On July 17, 1997, Judge DuBois referred to me for disposition the defendant's motion to compel discovery related to settlement of the Upsher-Smith case (Document No. 87). Plaintiff filed a memorandum in opposition thereto, and defendant filed a reply memorandum in support of its motion. Counsel presented oral argument on the issues on August 26, 1997.

II. DISCUSSION

In its motion, defendant seeks an order compelling plaintiff to produce any settlement agreement in the case Key Pharmaceuticals, Inc. v. Upsher-Smith Laboratories, Civil Action No. 95-6281 (D.N.J.) (the "Upsher Settlement Agreement").[1] Defendant claims that plaintiff has exhibited a pattern of asserting its patent against competitors' products which are clearly non-infringing, and this practice constitutes patent misuse, and renders plaintiff's patent unenforceable. (Amended Answer at ¶ 56; Def.'s Mem. Supp. Mot. at 1.)[2] Defendant argues that the Upsher Settlement Agreement is relevant to the issue of patent misuse in two respects. First, defendant contends that the agreement is expected to show that plaintiff settled the litigation against Upsher-Smith on terms "highly favorable to Upsher-Smith, illustrating how the suit against Upsher-Smith was as meritless as the suit against [defendant]." Id. at 2. Further, defendant argues that discovery is necessary because the settlement agreement itself may constitute further patent misuse, or an extension of the original patent misuse, if the terms of the Upsher Settlement Agreement further delay the entry of competition in the relevant product market. More specifically, according to 21 U.S.C.A. § 355(j)(4)(B)(iv) (West Supp. 1997), defendant and other competitors may be precluded from entering the market until 180 days after (1) Upsher-Smith notifies the Secretary of Health, Education and Welfare that it has commercially marketed its

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[1] In its motion, defendant also requested drafts of any settlement agreement, documents drafted in anticipation thereof, and a witness to testify pursuant to Fed. R. Civ. P. 30 (b)(6). At the oral argument, counsel for defendant stated that these items were requested because defendant did not know at the time the motion was filed whether a final settlement had been reached between the parties in the Upsher-Smith case. Since defendant now knows that a settlement agreement was signed in that case, it is willing to withdraw without prejudice its requests for drafts, documents drafted in anticipation of the settlement, and a deposition pursuant to Fed. R. Civ. P. 30(b)(6), and to seek merely a copy of the Upsher Settlement Agreement.

[2] "Patent misuse is an application of the equity doctrine of 'unclean hands' in the patent field and serves as a defense for an alleged infringer against a patentee." National Patent Dev. Corp. v. T. J. Smith & Nephew, Ltd., 865 F.2d 353, 356 n. 2 (D.C. Cir. 1989).

product, or (2) the court in the Upsher-Smith litigation decides that plaintiff's patent is invalid or not infringed. Defendant contends that the terms of the Upsher Settlement Agreement may delay the start of this 180 day period, and thereby further delay defendant's entry into the product market.

Plaintiff argues that the motion should be denied because defendant fails to meet the burden of proof required for a discovery request for this type of information. The parties agree that defendant's burden is set forth correctly in Fidelity Fed. Sav. and Loan Ass'n v. Felicetti, 148 F.R.D. 532 (E.D.Pa. 1993). In that case, the court considered, inter alia, "the strong Congressional policy behind Fed. R. Evid. 408 as well as the liberal discovery rules", and concluded that the burden is on the party seeking discovery to make a particularized showing "that the documents relating to the settlement negotiations are relevant and likely to lead to the discovery of admissible evidence." Id. at 534. The effect of this heightened requirement is to switch the burden of proof from the party in opposition to the discovery to the party seeking the information. Id. See also Doe v. Methacton School District, 164 F.R.D. 175, 176 (E.D. Pa. 1995).

"[R]elevancy is the touchstone of any discovery request." EEOC v. University of Pennsylvania, 850 F.2d 99, 979 (3d Cir. 1988), aff'd, 493 U.S. 182 (1990). However, Federal Rule of Civil Procedure 26(b)(1) does not demand that the matter sought to be discovered be relevant to the issues in the case, but requires only that the information be "relevant to the subject matter involved in the pending action." Fed. R. Civ. P. 26(b)(1); 8 Charles A. Wright, Arthur R. Miller, & Richard L. Marcus, Federal Practice and Procedure § 2008 at 99(1994). Courts should construe the requirement of relevancy "liberally and with common sense, rather than in terms of narrow legalisms." Id. at § 2008 at 107. Information that may be inadmissible as evidence at trial still may be discoverable, "if it is relevant to the subject matter of the action and there is a

reasonable possibility that the information sought may provide a lead to other evidence that will be admissible." Id. at § 2008 at 112-13. Moreover, discovery is not to be limited solely to matters arising prior to the commencement of the action; in certain circumstances, events occurring after the commencement of the action will "plainly be relevant." Id. at § 2008 at 105.

Applying the above principles to the defendant's discovery request, the court finds that defendant has met its burden of showing that the settlement agreement between plaintiff and Upsher-Smith is relevant and likely to lead to the discovery of admissible evidence. Federal Rule of Evidence 408 "is not an absolute ban on the admissibility of evidence that falls within its scope." 23 Charles A. Wright & Kenneth W. Graham, Federal Practice and Procedure § 5308 at 237 (1980). Evidence of a settlement agreement between plaintiff and Upsher-Smith Laboratories is inadmissible only "to prove liability for or invalidity of the claim and its amount." Fed. R. Evid. 408. If the settlement agreement is offered for another purpose, it may be admissible. See Advisory Committee's Note to Rule 408 ("Since the Rule excludes only when the purpose is proving the validity or invalidity of the claim or its amount, an offer for another purpose is not within the rule").

Clearly, the Upsher Settlement Agreement would be inadmissible to show that plaintiffs' action against Upsher-Smith "was as meritless as the suit against [defendant]."(Def.'s Memo Supp. Mot. at 2). Rule 408 expressly forbids the use of compromise evidence if offered to prove the invalidity of plaintiff's claims against Upsher-Smith and the defendant. If this were the only relevancy argument made to support defendant's discovery request, the court could easily deny it. However, defendant further argues that the settlement agreement itself may constitute further patent misuse, or a continuation of a pattern of patent misuse. Specifically, defendant contends that the terms of the Upsher Settlement Agreement may have intentionally

delayed the entry of competition in the relevant product market and violate the federal antitrust laws, and thereby constitute patent misuse. See Senza-Gel Corp. v. Seiffhart, 803 F.2d 661, 668 (Fed.Cir. 1986)(an antitrust violation by a patentee constitutes patent misuse). If this were the case, the compromise agreement itself would be illegal and would not be inadmissible under Rule 408. See Overseas Motors, Inc. v. Import Motors, Ltd., 375 F.Supp. 499, 537 and n. 128 (E.D. Mich. 1974)(evidence of settlement agreement is admissible if distinct antitrust claim arises from the agreement itself).

Defendant further argues that the Upsher Settlement Agreement may have the effect of delaying its entry into the product market. Defendant points out that, according to 21 U.S.C.A. § 355(j)(4)(B)(iv)(West Supp. 1997), defendant and other competitors may be precluded from entering the market until 180 days after (1) Upsher-Smith notifies the Secretary of Health, Education and Welfare that it has commercially marketed its product, or (2) the court in the Upsher-Smith litigation decides that the plaintiff's patent is invalid or not infringed. Since the Upsher-Smith litigation settled before trial, Judge Walls never decided the validity or invalidity of the '743 patent. Thus, defendant argues that the plaintiff may have intentionally delayed the start of this 180 day period, by placing restrictions on when Upsher-Smith may commercially market its product and thereby further delay defendant's entry into the market.[3] If this be the case, this agreement may be an illegal restraint on trade and constitute patent misuse. See generally, Morton Salt Co. v. G.S. Suppiger Co., 314 U.S. 488 (1942); Compton v. Metal Products, Inc., 453 F.2d 38 (4th Cir. 1971), cert. denied. 406 U.S. 968 (1972).

[3] As noted earlier, Upsher-Smith's ANDA was tentatively approved in March 1997, conditioned on the outcome of plaintiff's litigation against Upsher-Smith. Thus, as of the dismissal of the lawsuit, Upsher-Smith was free to market its Klor-Con M tablet, but has not done so to date.

Because the court finds that the above arguments satisfy the defendant's burden under Fed. R. Civ. P. 26(b)(1) of showing the relevance of the Upsher Settlement Agreement to the subject matter of the instant litigation, the court will order that plaintiff produce the settlement agreement. However, to protect the rights of both the plaintiff and Upsher-Smith to keep their settlement agreement confidential, the court will order that plaintiff produce the settlement agreement subject to all the provisions of the protective order entered by the Honorable Jan E. DuBois in this litigation. (Order dated July 3, 1996, Doc. No. 23). Furthermore, the court will not permit further discovery relating to the Upsher Settlement Agreement without a further order of the court.

An appropriate order follows.

BY THE COURT:

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THOMAS J. RUETER
United States Magistrate Judge

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O R D E R

AND NOW, this day of August, 1997, in accordance with the court's Memorandum of Decision filed this day, it is hereby ORDERED that

(1) Defendant's Motion to Compel Discovery Related to the Settlement of the Upsher Smith Case (Doc. No. 87) is GRANTED IN PART and DENIED IN PART.

(2) Within ten (10) days of the date of this order, plaintiff shall produce copies of all executed settlement agreements entered into by parties in the case of Key Pharmaceuticals, Inc. v. Upsher-Smith Laboratories, Inc., Civil Action No. 95-6281 (D.N.J.)

(3) Production of the settlement agreements by the plaintiff to the defendant shall be subject to all the provisions of the Protective Order entered by the Honorable Jan E. DuBois on July 3, 1996, (Doc. No. 23).

(4) No further discovery relating to the Upsher-Smith settlement agreements will be permitted, unless ordered by the Court.

BY THE COURT:

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THOMAS J. RUETER
United States Magistrate Judge